

04/12/2023	<a href="#">15785</a>	DEFENDANTS REPLY MEMORANDUM IN SUPPORT OF MOTION TO RECONSIDER AND VACATE CMO 36 AND TO STRIKE GENERAL EXPERTS IMPROPER TESTIMONY. (Reference: All Cases)(am) (Entered: 04/24/2023)
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**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA**

**In Re: TAXOTERE (DOCETAXEL)  
PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2740**

**SECTION “H” (5)**

**THIS DOCUMENT RELATES TO:  
ALL CASES**

**DEFENDANTS’ REPLY MEMORANDUM IN SUPPORT OF MOTION  
TO RECONSIDER AND VACATE CMO 36  
AND TO STRIKE GENERAL EXPERTS’ IMPROPER TESTIMONY**

The Court should reconsider and vacate CMO 36 under Rule 54(b).<sup>1</sup> The standard is not, as the PSC suggests, an “abuse of discretion” – the standard for appellate review.<sup>2</sup> Rather, the district court may “reconsider and reverse its decision for any reason it deems sufficient, even in the absence of new evidence or an intervening change in or clarification of the substantive law.” *Austin v. Kroger Texas, L.P.*, 864 F.3d 326, 336 (5th Cir. 2017) (citation omitted). Sufficient reasons exist here, and the PSC’s Opposition does not meaningfully dispute them.

First, CMO 36 does not contemplate returning every question of admissibility to the transferor courts. Instead, CMO 36 specifically limited expert preservation testimony “to the Court’s prior rulings as they relate to these witnesses, including the Court’s Rule 702 rulings.”<sup>3</sup>

Second, the PSC has no justification for its experts’ repeated violations of CMO 36. The PSC’s post-hoc explanations only highlight its non-compliance with the Court’s directions under CMO 36. Each opinion identified by Sanofi was either previously excluded, referenced topics

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<sup>1</sup> Sanofi has not yet taken any preservation depositions of its experts. If the Court vacates CMO 36, Sanofi requests that it do so for any additional preservation depositions of the PSC’s experts, while permitting Sanofi to proceed with at least two defense experts.

<sup>2</sup> Rec. Doc. 15767 at 4 (PSC’s Mem. in Opp. to Mot. to Reconsider and Vacate CMO 36 and to Strike General Experts’ Improper Test.) (citing *McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 701 (5th Cir. 2014)).

<sup>3</sup> Rec. Doc. 15763 at 14 (Suggestion of Remand) (citing Rec. Doc. 14925 at 1–2, 6 (CMO 36) (internal quotations omitted)).

ruled inadmissible by this Court, or was not disclosed in the operative expert report.

Third, the Court should vacate CMO 36 and strike Dr. Feigal and Dr. Madigan's undisclosed and inadmissible testimony because it is prejudicial to Sanofi. By its conduct, the PSC seeks to introduce excluded general expert opinions in the transferor courts.<sup>4</sup> The PSC's position contradicts CMO 36 and frustrates the purpose of MDL proceedings, which are designed to "prevent inconsistent pretrial rulings" and "conserve the resources of the parties, their counsel, and the judiciary." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 220 F. Supp. 3d 1360, 1361 (J.P.M.L. 2016).

#### **I. CMO 36 Limited Expert Preservation Deposition Testimony to Admissible Testimony Under this Court's Prior Rulings.**

CMO 36 set out critical parameters governing the preservation of general expert testimony. First, preservation depositions were subject "to the Court's prior rulings as they relate[d] to these witnesses,"<sup>5</sup> including "the Rule 702 rulings entered by this Court."<sup>6</sup> Second, the party proffering the expert needed to provide the expert report reflecting the opinions that each expert intended to proffer or provide a supplemental report with time for additional expert discovery.<sup>7</sup>

The PSC's position is that all issues of admissibility – including the admissibility of their experts' undisclosed or excluded opinions – should be left to the transferor courts.<sup>8</sup> This is wrong for two reasons.

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<sup>4</sup> Rec. Doc. 15767 at 5 ("If the transferor courts are inclined to revisit challenges under FRE 702 or *Daubert*, the PSC respectfully suggests that this is not an issue for the Court[.]"); *see also id.* at 13 ("The trial courts that will preside over future Taxotere trials where Dr. Madigan's preservation testimony may be played are fully capable of reviewing and permitting appropriate testimony via preserved testimony.").

<sup>5</sup> Rec. Doc. 14925 at 6.

<sup>6</sup> *Id.* at 2.

<sup>7</sup> *Id.* at 4.

<sup>8</sup> Rec. Doc. 15767 at 5.

First, the PSC's reading of CMO 36 conflicts with the Court's own statements. Although the Court noted that it was not pre-adjudicating issues of availability and admissibility under CMO 36, it explained that preserved general expert testimony would be taken subject to its rulings related to these experts:

In April 2022, the Court granted the PSC's Motion to Preserve Expert Testimony and later entered CMO 36. CMO 36 set out the protocols to preserve general expert testimony by video for potential use in remanded cases. **Under CMO 36, expert preservation deposition testimony is "subject to the Court's prior rulings as they relate to these witnesses," including the Court's Rule 702 rulings. In addition, the Court did not pre-adjudicate issues related to admissibility or availability—for example, whether the parties may introduce preservation deposition testimony at trial.** See Fed. R. Evid. 804. The parties have completed the preservation depositions of two of Plaintiffs' experts. Preservation depositions, including depositions of Sanofi's experts, may continue in this Court after the entry of this Order.<sup>9</sup>

The Court's Suggestion of Remand makes clear that preservation depositions are to be taken consistent with the Court's prior rulings as they relate to these experts – this is the condition precedent of CMO 36. The transferor courts may then decide additional issues of admissibility and availability before trial, such as whether the general expert is unavailable under Rule 804. But if all issues of admissibility were deferred to the transferor courts, including whether an expert's previously excluded opinions were admissible, then CMO 36's language limiting expert preservation testimony to the Court's prior rulings would be superfluous.

This is not the case. Before Dr. Laura Plunkett's preservation deposition, for example, the PSC disclosed that it intended to preserve Dr. Plunkett's testimony based on two expert reports that this Court had never addressed under Rule 702. When Sanofi raised this issue with the Court, the Court permitted Sanofi to file a Rule 702 motion addressing Dr. Plunkett's new corporate state

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<sup>9</sup> Rec. Doc. 15763 at 14 (emphasis added).

of mind and “bad company” opinions.<sup>10</sup> If all issues of admissibility were reserved for the trial court, then the Court would have permitted Dr. Plunkett’s preservation deposition to proceed without considering Sanofi’s Rule 702 challenges.

Second, the PSC’s current position goes against its previous representations to this Court. The PSC explicitly argued that “[p]reservation depositions, especially after *Daubert* determinations[,] will define the proper scope of that testimony.”<sup>11</sup> The PSC also acknowledged that preservation depositions would only be efficient if the general expert testimony was limited to the Court’s previous rulings on these experts:

This Court has overseen four different sets of briefing, four hearings on *Daubert* motions challenging the same experts and we’ve heard the same arguments time and time again. We don’t need to hear them or we don’t need to see them compounded by 200 this first round and another 200 the next round. This should be decided once and once only. And it conserves resources for the parties, for counsel, and the judiciary.<sup>12</sup>

The PSC should be held to these limitations.

## **II. The PSC Has No Justification for Its Experts’ Repeated Violations of CMO 36.**

Sanofi identified multiple opinions that Dr. Feigal and Dr. Madigan offered during their preservation depositions that violated CMO 36. Although the PSC attempts to rationalize these opinions in its Opposition, each opinion did not comply with CMO 36 because the Court previously excluded it, the opinion referenced topics ruled inadmissible by this Court, or the expert failed to disclose the opinion in the report identified for the preservation deposition.

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<sup>10</sup> *Id.* at 37.

<sup>11</sup> Rec. Doc. 12729-1 at 2 (PSC’s Mot. to Preserve Expert Test.).

<sup>12</sup> Rec. Doc. 15673-2 (Ex. A to Sanofi’s Mot. to Reconsider and Vacate CMO 36 and to Strike General Experts’ Improper Test., Hr’g Tr. 8:11–18 (Mar. 8, 2022)).

**Dr. Feigal's Causation Opinions on Other Chemotherapies:** Dr. Feigal conducted a Bradford Hill analysis for Taxotere.<sup>13</sup> But at Dr. Feigal's preservation deposition, the PSC elicited causation opinions from Dr. Feigal on other chemotherapies, including Adriamycin and Cytosan:

Q. With regard to Adriamycin, have you investigated whether or not reliable scientific evidence establishes that Adriamycin causes permanent chemotherapy-induced alopecia?

A. No, I do not have evidence to support that.

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Q. Okay. Did you find any reliable scientific evidence that said from between 1959 to 2004, when Taxotere was approved for early-stage breast -- use of adjuvant care in early-stage breast cancer, that cyclophosphamide can cause permanent chemotherapy-induced alopecia?

MR. MOORE: Object to form.

A. No.<sup>14</sup>

The PSC suggests that Dr. Feigal's testimony is consistent with her previous testimony. It is not. An opinion that no evidence exists that a drug can *cause* a condition is a *causation* opinion.<sup>15</sup> And Dr. Feigal conceded that she did not conduct an analysis in her expert report to determine whether Adriamycin and Cytosan cause PCIA.<sup>16</sup> Under CMO 36, Dr. Feigal was limited to opinions in her expert report, which the PSC violated by eliciting causation opinions on other chemotherapies.

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<sup>13</sup> See Rec. Doc. 15673-6 (Ex. E to Sanofi's Mot. to Reconsider, Feigal Dep. 141:4-25 (Sept. 1, 2020)).

<sup>14</sup> Rec. Doc. 15673-3 (Ex. B to Sanofi's Mot. to Reconsider, Feigal Dep. 44:1-46:2 (Jan. 26, 2023) (filed under seal)).

<sup>15</sup> The PSC further notes that Dr. Feigal did not conduct an analysis that other chemotherapies cause PCIA "[b]ecause there wasn't sufficient data to do that analysis." Rec. Doc. 15767 at 7. The inference, then, is that other chemotherapies do not cause PCIA – an inference unsupported because Dr. Feigal did not conduct a Bradford Hill analysis for any other chemotherapies besides Taxotere.

<sup>16</sup> Rec. Doc. 15673-4 (Ex. C to Sanofi's Mot. to Reconsider, Feigal Dep. 262:8-24 (Jan. 27, 2023) (filed under seal)).

**Dr. Feigal’s References to Excluded Evidence:** By prior opinion, the Court precluded evidence of Sanofi’s labeling changes.<sup>17</sup> Yet the PSC suggests Dr. Feigal’s testimony on this subject at her deposition was justified because it unilaterally determined that Sanofi’s questioning “opened the door.”<sup>18</sup> Sanofi, however, questioned Dr. Feigal on Sanofi’s responses to regulatory agencies and the underlying case reports in TAX 316. None of Sanofi’s questions asked Dr. Feigal to opine on Taxotere’s labeling. The PSC’s justification for Dr. Feigal’s excluded opinions only highlights the inefficiencies that warrant vacating CMO 36 – that is, if the PSC’s experts unilaterally believe that Sanofi has “opened the door,” then previous rulings excluding opinions or limiting evidence are effectively vacated.

**Dr. Madigan’s Causation Opinions:** The PSC asserts that Dr. Madigan “does not state that Taxotere ‘causes’ PCIA, but rather that there is a statistical association and *inference* of causation between docetaxel and permanent chemotherapy-induced alopecia.”<sup>19</sup> This raises two obvious problems.

The first is that Dr. Madigan *did* state that Taxotere causes PCIA: “I concluded that there is adequate statistical evidence that docetaxel causes permanent/irreversible alopecia.”<sup>20</sup> The Court previously excluded this exact opinion.<sup>21</sup> The second is that the Court only permitted Dr. Madigan to opine on a statistical association.<sup>22</sup> The Court has never permitted Dr. Madigan to opine on whether there is an “inference of causation” – a phrase that appears nowhere in Dr.

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<sup>17</sup> Rec. Docs. 8201 at 6 (Order and Reasons in *Earnest*); 13260 at 8 (Order and Reasons in *Kahn*).

<sup>18</sup> Rec. Doc. 15767 at 9.

<sup>19</sup> *Id.* at 10.

<sup>20</sup> Rec. Doc. 15673-7 (Ex. F to Sanofi’s Mot. to Reconsider, Madigan Dep. 43:23–44:12 (Nov. 14, 2022) (filed under seal)).

<sup>21</sup> Rec. Doc. 12098 at 4 (Order Granting in Part and Denying in Part Defs.’ Mot. to Exclude Expert Test. of Dr. David Madigan).

<sup>22</sup> *Id.* at 5.

Madigan’s June 2020 expert report. Instead, the Court previously cautioned Dr. Madigan to “take care to state only that the evidence shows an association between [Taxotere and PCIA].”<sup>23</sup> The PSC has elicited an opinion from Dr. Madigan that “improperly encroaches on the second prong of the general causation inquiry—a prong that Dr. Madigan has not analyzed.”<sup>24</sup>

**Dr. Madigan’s “Chemo 2” Analysis:** The PSC concedes that, as to Dr. Madigan’s “Chemo 2” analysis, “Dr. Madigan did not perform an analysis in order to offer any new opinion on his direct testimony (here or in the *Kahn* trial) and as a result did not include any such opinion in any of his reports.”<sup>25</sup> CMO 36 limited Dr. Madigan to the opinions in the report the PSC identified for his preservation deposition.<sup>26</sup> And if the PSC intended to have Dr. Madigan provide his “Chemo 2” analysis during his preservation deposition, CMO 36 permitted the PSC to serve a supplemental expert report to provide Sanofi with fair notice and an opportunity to conduct a discovery deposition on this opinion.<sup>27</sup>

**Dr. Madigan’s Regulatory Opinions:** The PSC does not address Dr. Madigan’s improper regulatory opinions anywhere in its Opposition.<sup>28</sup> Nor could it. Although the PSC elicited testimony from Dr. Madigan about a drug manufacturer’s monitoring obligations and his speculation as to the difference in event reporting between Sanofi’s database and the FAERS database, Dr. Madigan has never disclosed these opinions in his expert report.<sup>29</sup>

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 4.

<sup>25</sup> Rec. Doc. 15767 at 12.

<sup>26</sup> Rec. Doc. 14925 at 4. At the risk of stating the obvious, CMO 36 did not permit experts to provide undisclosed opinions on cross-examination.

<sup>27</sup> *Id.*

<sup>28</sup> *See generally* Rec. Doc. 15767.

<sup>29</sup> Rec. Doc. 15673-8 (Ex. G to Sanofi’s Mot. to Reconsider, Madigan Dep. 411:8–15, 423:21–424:1 (Nov. 15, 2022) (filed under seal)).



### **III. The PSC’s Repeated Violations of CMO 36 – and the Risk of Future Violations – Warrants Vacating CMO 36 and Striking Dr. Feigal and Dr. Madigan’s Undisclosed and Inadmissible Testimony.**

CMO 36 contemplated preserving general expert testimony consistent with the Court’s prior rulings “to avoid further duplication of efforts, to appropriately limit expenses to the parties and wasting of resources, to allow the PSC to create a trial package, and to promote the efficient preparation for eventual remand.”<sup>30</sup> By providing expert testimony that violates CMO 36, however, the PSC hopes to introduce excluded general expert opinions in the transferor courts. To that end, the PSC suggests that “[i]f the transferor courts are inclined to revisit challenges under FRE 702 or *Daubert*, the PSC respectfully suggests that this is not an issue for the Court.”<sup>31</sup> But this Court has already ruled on these issues, which are subject to significant deference in the transferor courts. *See In re Ford Motor Co.*, 591 F.3d 406, 411 (5th Cir. 2009).

The PSC’s suggestion that the transferor courts re-rule on expert challenges runs counter to the very goals of this MDL – to “prevent inconsistent pretrial rulings” and “conserve the resources of the parties, their counsel, and the judiciary.” *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 220 F. Supp. 3d at 1361. And by introducing excluded opinions under the auspices of CMO 36, Sanofi faces substantial prejudice in the transferor courts because these experts’ improper testimony will carry the perceived imprimatur of admissibility under CMO 36 when, as noted above, this is not the case. Continuing to take general expert preservation depositions will only compound the potential for prejudice to Sanofi. As a result, the Court should vacate CMO 36 and strike Dr. Feigal and Dr. Madigan’s undisclosed and inadmissible testimony.

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<sup>30</sup> Rec. Doc. 14925 at 7.

<sup>31</sup> Rec. Doc. 15767 at 5; *see also id.* at 13 (“The trial courts that will preside over future Taxotere trials where Dr. Madigan’s preservation testimony may be played are fully capable of reviewing and permitting appropriate testimony via preserved testimony.”).

**CONCLUSION**

Sanofi has proceeded with CMO 36 in good faith. Dr. Feigal and Dr. Madigan's depositions, however, make clear that any perceived efficiencies have been overwhelmed by the PSC's introduction of undisclosed and inadmissible testimony, which will require substantial burden and expense to litigate in the transferor courts. For these reasons, the Court should vacate CMO 36 and strike Dr. Feigal and Dr. Madigan's undisclosed and inadmissible testimony.

Respectfully submitted,

/s/ Douglas J. Moore

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 11, 2023, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to all counsel of record.

/s/ Douglas J. Moore